

REMARKS/ARGUMENTS

Applicant notes that they have amended claims 1, 3, and 8, and added new claims 9 and 10. New claim 9 is a combination of current claims 1 and 3; and claim 10 is a combination of current claims 1, 3, and 4. Reconsideration of the present application is requested in light of the Applicant's amendments and remarks, as presented below.

Drawings

The Examiner objected to the drawings under 37 CFR 1.83(a), contending that the drawings did not show every feature of the invention specified in the claims, specifically the lug engagement means (Claim 4) and accessories (Claim 8). By way of response, Applicant has cancelled Claim 8, thereby rendering this rejection moot with respect to Claim 8. With respect to Claim 4, Applicant contends that the feature, "lug engagement means," although not referenced specifically by name in the specification, is described in the specification in the description of Figures 1-3.

A 'lug,' in a mechanical context, is used to refer to a projecting piece to which anything, such as a rod, is attached, or against which anything, such as a wedge or a key, bears, or through which a bolt passes. Applicant respectfully directs the Examiner's attention to the Specification, p. 6. ll. 27-31, describing features shown in Figures 1-3. Specifically, the Specification notes: "[i]t will be noted that the syringe disposal device 10 has a slot 70 formed in its wall 14a proximate engaging face 16a, forming the remaining portion of engaging means 20, through which an outer portion of flange portion 38a extends in the engaged position." Applicant submits to the Examiner that the foregoing description describes a functional apparatus that may also be referred to as 'lug engagement means.' Accordingly, Applicant submits that the feature, "lug engagement means," is shown in the drawings and accordingly the drawings satisfy the 37 CFR 1.83(a) requirement. Withdrawal of this objection is respectfully requested.

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Rejection under 35 U.S.C. 112, second paragraph

The Examiner has rejected claim 3 under 35 U.S.C. 112, second paragraph, for being indefinite for the reason that the term “at the transition” should be “at a transition.” Applicant has amended claim 3 in accordance with the Examiner’s suggestion and respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. 102(b)

Teicher (U.S. 5,451,213)

The Examiner has rejected claims 1-2 and 4-6 under 35 U.S.C. 102(b) over Teicher. The Examiner contends that Teicher discloses a device comprising a needle encapsulating portion, a syringe barrel encapsulating portion and a retention portion.

For a proper rejection under 35 U.S.C. 102(b), it is clear that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. Of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant respectfully submits that the Teicher reference does not teach all of the elements comprising the Applicant's invention, as claimed in claims 1-2 and 4-6.

For greater clarity, Applicant has amended claim 1 to recite in the body of the claim that the transversely extending portion which engages with the instant disposal device is on the barrel or plunger of the syringe. Claims 1-2 and 4-6 are directed to a syringe disposal device for disposing of a single syringe. The syringe contains a needle, a barrel, and a plunger. Importantly, on the barrel or plunger of the syringe there is a transversely extending portion or flange. Elements of the disposal device of the present invention include the following: (a) a needle encapsulating portion; (b) a syringe barrel encapsulating portion; and (c) a syringe retention portion. The syringe retention portion (c) has a greater external dimension along substantially its whole length than the outer diameter of the syringe encapsulating portion (b) and the needle encapsulating portion (a). The syringe retention portion has an open end for insertion of a syringe and an opposed end communicating the syringe retention portion with the syringe barrel encapsulating portion. Engagement means are provided at, or proximate the opposed end of the syringe retention portion

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of the disposal device, for retaining the syringe via the flanged portion of the barrel or plunger after the passage of the barrel or plunger past the engagement means by interference fit. The hub of the needle is not engaged by the syringe retention portion of the instant disposal device.

Teicher, in contrast, teaches a device which does not contain all of the elements of the instant device. Teicher's device is not designed to engage the entire syringe. Teicher teaches a disposable protective device for syringe needles which includes a needle retainer formation with the sheath engageable with the hub of a needle. Specifically, it is the hub of the needle that is retained within the device. See Teicher, Figure 5, showing that the needle, including its hub, is inserted into sheath 10 with the annular rib 8 of the hub located between the retainer rib 20 and the locking shoulder 13 (see also col. 4, ll. 62-65). The effect of this is to "irreversibly lock the needle within the sheath once inserted therein." (Col. 2, ll. 15-17.)

Although the instant device, like Teicher, also retains the needle within the disposal device, the disposal device of the present invention, unlike Teicher, has retention means provided for retaining the entire syringe, not just the needle, within the disposal device. Specifically, Teicher does not teach a device containing the following element, as provided in claim 1, as amended:

engagement means being provided at or proximate, said opposed end of said syringe retention portion for retaining a syringe within the disposal device after passage of said transversely extending portion of the syringe barrel or plunger past said engagement means by interference fit.

As amended, claim 1 makes clear that the Applicant's disposal device contains a retention means for the transversely extending portion of a syringe barrel or plunger, an element that is not taught or suggested by Teicher, who instead provides for retention of the needle only. The claim amendment further clarifies the fact that the instant device retains a transversely extended portion of the syringe distal to the needle or needle hub.

Applicant submits that, as Teicher does not teach each and every element of the invention as taught and claimed, and as such, respectfully request that the Examiner withdraw his 35 U.S.C. 102(b) rejection of claims 1-2 and 4-6 over Teicher.

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Patrick (FR 2 650 511)

The Examiner has rejected claims 1-6 under 35 U.S.C. 102(b) over Patrick. The Examiner contends that Patrick discloses a device comprising a needle-encapsulating portion, a syringe barrel encapsulating portion and a retention portion.

As discussed above for the rejection under Teicher, a proper rejection under 35 U.S.C. 102(b) requires that the reference teach each and every element of the invention as claimed. Applicant respectfully submits that the Patrick reference does not teach each and every element of the Applicant's invention, as claimed in claims 1-6.

Applicant notes that claim 1 teaches a syringe disposal device with a number of elements. Applicant wishes to direct the Examiner's attention to the portion of claim 1 relating to the syringe retention portion. Applicant recites that the syringe retention portion has a "greater external dimension along substantially its whole length than an outer diameter of the syringe barrel encapsulating portion and the needle encapsulating portion." Applicant notes that Patrick teaches a disposal device in the form of a plastic cylinder (See Patrick, page 2, ll. 20-25). Patrick's device does not have a greater external dimension in the syringe retaining portion compared to the syringe barrel encapsulating portion, in contrast to claim 1.

Claim 1 of the instant application also recites the limitation that the retention of the syringe within the instant disposal device is by interference fit. An interference fit may be described as a fit in which two toleranced mating parts will always interfere when assembled because the "male" part is larger than the "female" part. An interference fit fixes or anchors the two parts as if they were one. There is no travel of the syringe within the disposal device once the user has pressed the syringe into the device and accomplished the interference fit. In contrast, Patrick teaches a lip within their disposal device shaped so as to cover the whole edge of the upper part of the syringe. Patrick's method of restraining the syringe is not an interference fit. Rather, Patrick teaches a protrusion that blocks travel in one dimension. Patrick's retention means will still allow travel by the syringe further into the device. Accordingly, Patrick does not teach retention of a syringe by interference fit as instantly claimed. Applicant respectfully submits that Patrick does not teach each and every element as claimed in claims 1-6 and respectfully request withdrawal of the rejection.

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Although Applicant believes that claims 2-6 are allowable as being dependent from an allowable independent claim, Applicant would like to provide additional arguments relating to novelty of these dependent claims. In particular, claim 2 recites that the syringe retention portion is tapered; claim 3 recites a morse taper at the transition between the syringe barrel encapsulating portion and the needle encapsulating portion (providing an additional retention means for the syringe); claim 4 recites a lug engagement means; claim 5, an annular engaging face; claim 6, wherein the body of the device is of tapered form. These elements are not taught by the Patrick reference. Applicant accordingly respectfully submits that Patrick does not teach each and every element as claimed in claims 2-6 and respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. 103(a)

Teicher (U.S. 5,451,213) in view of Faulseit (U.S. 3,342,310)

The Examiner has rejected claim 3 under 35 U.S.C. 103(a) over Teicher in view of Faulseit. The Examiner contends that Faulseit teaches a syringe holder with a taper in the needle-encapsulating portion.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 180 USPQ 580 (CCPA 1974). Applicant respectfully submits that all the claim limitations of claim 3 are not taught by the combination of the references. Specifically, Applicant submits that claim element, 'morse taper,' is not taught by the Faulseit reference.

Applicant respectfully disagrees with the Examiner's characterization of the Faulseit reference as teaching a morse taper. Applicant acknowledges that the needle encapsulating portion of the Faulseit device tapers, however, in claim 3 Applicant recites a "morse taper," which is not the same thing as a taper. A morse taper refers to a stepped arrangement such as the one seen in the instant patent application's Figure 4. Such an arrangement actually engages with and causes retention by force of friction.

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Applicant directs the Examiner's attention to claim 3, which for the purposes of clarity has been amended to recite that the morse taper is for engaging the needle hub. Applicant submits that Fauseit does not disclose a structure corresponding to Applicant's morse taper. Accordingly, Applicant submits that the Examiner has not established *prima facie* obviousness for claim 3 and respectfully request withdrawal of this rejection.

Teicher (U.S. 5,451,213) in view of Mueller (U.S. 4,954,239)

The Examiner has rejected claims 7-8 as being unpatentable under 35 U.S.C 103(a) over Teicher in view of Mueller. The Examiner contends that Mueller teaches a kit comprising a container and other accessories in combination with a syringe.

As discussed above for the Examiner's 35 U.S.C. 102(b) rejection over Teicher, Teicher does not contain all of the elements of claim 1. In particular, Teicher lacks a retention means for the transversely extending portion of a syringe barrel or plunger as taught and claimed by the instant invention. Mueller's kit, comprising a container with other accessories therein necessary for use, does not supply the missing elements of Teicher. Accordingly, Applicant respectfully requests the withdrawal of the Examiner's rejection of claims 7-8 under 35 U.S.C 103(a) over Teicher in view of Mueller.

Patrick (FR 2650511) in view of Mueller (U.S. 4,954,239)

The Examiner has rejected claims 7-8 as being unpatentable under 35 U.S.C 103(a) over Patrick in view of Mueller. The Examiner contends that Mueller teaches a kit comprising a container and other accessories in combination with a syringe.

As discussed above in Applicant's traversal of the Examiner's 35 U.S.C. 102(b) rejection over Patrick, Patrick does not contain all of the elements of claim 1. In particular, Patrick lacks a syringe retention portion having a greater external dimension along substantially its whole length than an outer diameter of the syringe barrel encapsulating portion and the needle encapsulating portion, as well as an interference fit between the syringe and the instant syringe disposal device,

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both of which are taught by Applicant. Mueller's kit, comprising a container with other accessories therein necessary for use of the syringe disposal device, does not supply the missing elements of Patrick. Accordingly, Applicant respectfully requests the withdrawal of the Examiner's rejection of claims 7-8 under 35 U.S.C 103(a) over Patrick in view of Mueller.

New Claims 9-10

Applicant, with this Amendment and Response, has presented new Claims 9 and 10. New Claim 9 is a combination of current Claims 1 and 3 (as presently amended herein); and Claim 10 is a combination of current Claims 1, 3, and 4 (as presently amended herein). Applicant believes new Claims 9 and 10 are allowable for the reasons put forth in Applicant's arguments above relating to Claims 1, 3, and 4.

Applicant has attempted to address all of the Examiner's concerns as set forth in the February 12, 2004, Office Action. In the event that the Examiner has any additional concerns regarding the claims, the Examiner is encouraged to contact the below named attorney at (303) 863-2977 to discuss the issues.

Respectfully submitted,
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